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Research- & Bolar exemptions in the U.S. and Europe: Recent developments and possible scenarios

Report on CeBIL webinar III in the webinar series on “Reinterpreting TRIPS in the Life sciences”[□]

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Introduction

Our third webinar on 29th November 2018, focused on research exemptions and Bolar provisions in the U.S. and Europe. Legal scholar Jacob Sherkow from New York Law School and Martin Dræbye Gantzhorn and Klaus Ewald Andersen, both partners in the law firm Bech-Bruun, provided presentations. The Webinar was moderated by Prof. Timo Minssen, and was organized by Jakob Wested in collaboration with the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

In October 2017, the EU Commission announced a consultation on supplementary protection certificates (SPCs), research exemptions and Bolar-provisions. These three features in the legal and regulatory landscape of Life Science have a controversial history, both in courts and in the political process leading to their various implementation in jurisdictions around the globe. During the webinar, we discussed recent developments with a special focus on the so-called Bolar-provisions. Granting generic and biosimilar manufacturers limited access to patented inventions during the market authorization procedure is important to allow them to have a marketable product upon patent expiry. However, the boundaries of this right are still unclear, and substantial differences seem to persist between various jurisdictions. Thus, the intersection of the provisions of the TRIPS agreement¹ and the interpretation of the various research exemptions and Bolar-provisions implemented in national legislations has been a source of uncertainty and controversy for many years.

The webinar provided an update on the latest developments on Bolar-provisions and the intersection with relevant TRIPS provisions, identified some of the unresolved issues and presented some comments on possible future developments in this important and exciting area of law.

[□] In a series of webinars in 2017 and 2018 international experts set focus on the TRIPS agreement and the life sciences. The aim of the webinars was to bring together scholars, industry and practitioners in constructive dialogue on pressing legal issues arising at this intersection IPR and innovation in this field. The webinar series were supported and co-funded by The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) project and the University of Copenhagen's Faculty of Law.

¹ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

1. Background

Defining and achieving a suitable scope of patent protection that accommodates the dual interests of the patent holder, research communities, competitors and society is an essential and recurring “leitmotif” in patent law. The delicate demarcation between patent rights exclusionary effects, competition law and the socio-economic function of patents to incentivize innovation and the disclosure of technological knowledge, form central themes in addressing the interests of the individual inventor and the collective of the society. Research exemptions and the so-called Bolar provisions forms a complex addendum to the fundamental “quid pro quo” of disclosure for protection enshrined in patent law.

The idea of a research exemption relates to the patent’s function of protecting the patent holder against *commercial* use of the patented invention. The central idea is that a distinction can be made between commercial and non-commercial use of the invention. A typical example for this would be university researchers using a patented invention with a focus on knowledge generation rather than commercialization. The application of such an exemption to the exclusive rights of the patent holder revolves on an interpretation of the “commercial” and “non-commercial” use. However, such interpretation also reflects basic policies and assumptions related to the governance of innovation systems and its institutions, e.g. by granting broader scope of protection for initial, upstream inventions while lessening the possibility and incentive for further exploration and downstream improvement of the initial pioneer invention². Access to research tools is another controversial topic when addressing research exemptions from patent protection.

While the research exemption has a long history, the Bolar exemption³ is of a more recent origin. The central idea of a Bolar exemption is to allow competitors to experiment with a patented invention in order to achieve market authorization for a generic or biosimilar before the term of patent protection has elapsed. Particularly in the pharmaceutical sector, the conduct of R&D and clinical trials needed even for a generic product to get a marketing approval may take years. Thus, if a competing generic or biosimilar producer were not allowed to start this work before the patent protection for the original product had elapsed, the *de facto* protection of the patent would extend beyond the 20 years of protection granted by the patent. However, as with the research exemption, there are several interpretive uncertainties in the application of Bolar style provisions.

Both the Bolar and the research exemptions have given rise to substantially different interpretations among different jurisdictions. Many European jurisdictions provide for rather broad research exemptions, whereas the research exemption for patent infringement has traditionally been interpreted very narrowly in the U.S. where the Hatch-Waxman act introduced Bolar-type provisions

² Norman Siebrasse and Keith Culver, ‘The Experimental Use Defense to Patent Infringement: A Comparative Assessment’ (2006) 56 The University of Toronto Law Journal 333.

³ “Bolar exemption” is the popular phrase referring to the statutory exemptions from patent infringement introduced with the Hatch-Waxman act in 1984, following a much contested case between Roche products v. Bolar pharmaceuticals, 733 F.2d 858 (U.S. Fed. Cir. 1984).

in 1984. This regulatory initiative was subsequently adopted by the European Union and is currently implemented in Directive 2001/83/EU as amended by Directive 2004/27/EU. Though the purpose is the same and the codification very similar in these two jurisdiction, the interpretation by courts has been very different in U.S. and Europe.

Against this background, the following sections will *first* provide the U.S. perspective on available exemptions for use of patented inventions considering the common law and the statutory exemptions from infringement based on the webinar presentation by *Jacob Sherkow*. *Secondly*, a European perspective will be provided, based i.a. on the presentation and comments provided by *Martin Gantzhorn* and *Klaus Madsen*, and *thirdly*, some of the unresolved issues pertaining to the application and interpretation of the exemptions will be presented. *Finally*, some nascent trends addressing the challenges are discussed in the concluding remarks.

2. U.S. Perspective

In U.S. the definition of direct infringement of a patent is set out in § 271 of the patent statute⁴. This statute has been interpreted by the US courts on numerous occasions and the general picture is that it is interpreted very broadly. An illustration of this broad interpretation of infringement is found in practice pertaining to farmer's infringement of patents on genetically modified seeds. In *Bowman v. Monsanto*⁵ a farmer were found to have infringed Monsanto's patents on genetically modified seeds by using seeds purchased from a local grain elevator where other local farmers had sold their crop (and grains), which turned out to be propagated from Monsanto's patented seeds. On the flip side of this broad approach to patent infringement, the exemption to the patent protection following from common law is very narrow and limited to acts of mere entertainment, curiosity or strictly philosophical enquiry⁶. Thus, not even acts performed to test whether a disclosed invention actually performs the functions it claims are exempted from the scope of patent protection. The broad interpretation of infringement and the virtual lack of an exemption even for research purposes at a research institution⁷ outlines a general landscape where substantial protection is provided for the initial inventor and little room is left for others to test, experiment and further develop the initial invention without purchasing a license from the patent proprietor.

2.1 Statutory exemption – Bolar

Now we turn from the common law research exemption to the statutory exemption found in the Hatch-Waxman act⁸, often referred to as the Bolar provision⁹. Here, a seemingly quite expansive and robust interpretation of the exemption can be found. Whereas the common law research exemption only allowed room for mere philosophical inquiry, the Bolar exemption covers all activity *reasonably related* to the development and submission of information under a federal law, which regulates the

⁴ Title 35 of the United States Code.

⁵ *Bowman v. Monsanto Co.* 133 S.Ct. 1761 (2013).

⁶ *Whittemore v. Cutter*, 29 Fed. Cas. 1120 (C.C.D. Mass. 1813).

⁷ See e.g. *Madey v. Duke University*, 037 F.3d 1351 (Fed. Cir. 2002).

⁸ Act. 98 Stat. 1585 (1984) § 271(e)(1). The Hatch-Waxman Act is formally known as the Drug Price Competition and Patent Term Restoration Act.

⁹ [Anthony Tridico](http://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html), 'Facilitating generic drug manufacturing: Bolar exemptions worldwide' WIPO Magazine (June 2014) 17. Available at: http://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html.

manufacture, use, or sale of drugs or veterinary biological products.¹⁰ The exemption applies to both generic and new drugs¹¹ as well as medical devices¹². The Bolar exemption provides a safe harbour for pre-marketing activities. However, it may also provide a safe harbour for certain post-marketing activities, though the extend of this protection is a more delicate matter. The current situation seems to be that the Bolar Safe harbour does not apply per se to post-approval routine activities such as batch testing¹³. However, if post-approval activities are conducted due to specific requirements of the FDA, they may be covered by the Bolar exemption¹⁴ though subject to a “more critical analysis in the post-approval context.”¹⁵

Though the US Bolar exemption has been interpreted broadly, it still seems to be in a state of flux and the exact demarcations of the application of the safe harbour are still a tricky issue, particularly in the post-approval context, where its applications seems to be highly fact-specific. It is also yet to be determined to what extend pre-clinical activities, such as early stage high throughput screening of compounds, or in vitro assays, can be considered “reasonably related” to the development and submission of information under a federal law and thus benefit from the Bolar exemption safe harbour¹⁶.

2.2 Medical practitioners

A second statutory exemption in US law concerns the immunity of physicians from damages and injunctions incurred by a patent infringement¹⁷. The exemption grants immunity to medical practitioners for the performance of a medical or surgical procedure on a body. However, the immunity does not extend to the use of patented machines, manufacture or compositions of matter by medical practitioners, nor the practice of a patented use of a composition of matter or the practice of a process in violation of a biotechnology patent¹⁸. Historically, it has been considered derogatory to the professional character of physicians to hold a patent¹⁹. However, over time this norm has softened. In 1940 the ban on patenting was revised, and it was no longer considered “*unprofessional to receive remuneration from patents or copyrights on surgical instruments, appliances, medicines, foods, methods or procedures.*”²⁰ In 1955 the patenting of surgical instruments, appliances and medicines

¹⁰ 35 U.S.C §271(e)(1). This provision overturned the Federal Circuit decision in Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc., 733 F.2d 858 (1984), which found that the traditional experimental use exemption to patent infringement (35 U.S.C. § 271(a)) did not apply to pre-market testing done by a generic manufacturer and submitted to a regulatory agency.

¹¹ US Supreme Court, Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005).

¹² US Supreme court, Eli Lilly and Co. v. Medtronic, 496 US 661 (1990).

¹³ United States Court of Appeals for the Federal Circuit 659 F.3d 1057 (Fed. Cir. 2011).

¹⁴ Momena Pharma., Inc. v. Teva Pharma. USA Inc., Nos. 2014-1274, -1277, -1276, and -1278 (Fed. Cir. Nov. 10, 2015).

¹⁵ Momena II, 809 F.3d at 621. See generally Brian Coggio and Ron Vogel, ‘Federal Circuit Limits Safe Harbor for Post-Approval Conduct’ *LAW360* (Nov. 17, 2015). < <https://www.law360.com/articles/727923/fed-circ-limits-safe-harbor-for-post-approval-conduct>> Accessed 15 August 2018.

¹⁶ Anthony Tridico (n 9). In *Integra v. Merck* (n 11), the US Supreme Court launched a surprisingly broad interpretation of what could be considered “reasonably related” under the Bolar exemption.

¹⁷ 35 U.S.C § 287 (c).

¹⁸ 35 U.S.C § 287 (c)(2)(A)(i-iii).

¹⁹ AM. MED. ASS'N, CODE OF MEDICAL ETHICS § 4 (1847).

²⁰ Organizational Section Proceedings of the New York Session (1940) 114 JAMA 2557, 2567. Available at: http://jama.jamanetwork.com/data/Journals/JAMA/7654/jama_114_26_014.pdf.

was allowed with the caveat that the remuneration should not retard or inhibit research or restrict the benefits derivable therefrom²¹. Finally, in 1957 direct references to patents were removed from the American Medical Association's (AMA) ethical code, though reference to the 1955 position on patent was included in a compilation of supplementary sections²². In the 1950's and in subsequent decades various claims covering methods related to medical procedures were nevertheless successfully patented, though such claims were still rare²³. In the subsequent decades, however, the idea that patents could help facilitate medical advances prevailed. Thus, in 1990 Dr. Samuel Pallin received a patent on an improvement of cataract surgery technique and subsequently enforced it on Dr. Jack Singer²⁴. This led to a storm of protests from the community of medical practitioners, which led the U.S. Congress to pass the immunity for medical practitioners from patent infringement enshrined in §287(c)²⁵.

Thus, in the U.S., the *common law exemption* provides a very narrow exemption. The Hatch-Waxman acts *Bolar exemption* provides a robust and quite broad exemption to most activities performed before market approval and some activities after marketing approval that is reasonable related to obtaining such approval. Finally, there is a *safe harbour for physicians* consisting of immunity from injunction and damages in relation to the conduct of medical procedure or surgery on the body.

3. European perspective

Research- and Bolar exemptions and legal mechanisms directed to enable medical practitioners' freedom to operate are also provided for in Europe. This section will shortly point to some central differences between the European and the U.S. approach to research exemptions and the protection of medical practitioners, and then turn to a consideration of the current issues pertaining to the Bolar exemption in Europe.

3.1 Exemptions for research and methods of treatment

Many European countries have implemented research exemptions in their national legislations in compliance with Article 30 of the TRIPS agreement. Article 30 TRIPS, allows member states to provide limited exceptions to the exclusive rights conferred by a patent, in respect of normal exploitation and legitimate interest of the patent holder and third parties. Considering this, there are significant differences in the scope of the research exemption in the various European jurisdictions²⁶,

²¹ American Medical Association, Report of Council on Constitution and Bylaws, 1955 PROC. AM. MED. ASS'N CLINICAL MEETING 111, available at http://ama.nmtvault.com/jsp/viewer.jsp?doc_id=ama_arch%2FHOD00001%2F00000059&page_name=129.

²² AM. MED. ASS'N, PRINCIPLES OF MEDICAL ETHICS 1957 (1958), available at https://www.ama-assn.org/sites/default/files/media-browser/public/ethics/1957_principles_0.pdf. See also Kathrine Strandburg, 'Legal but Unacceptable: Pallin v. Singer and Physician Patenting Norms' in Rochelle Dreyfuss and Jane Ginsburg (eds), *Intellectual Property at the Edge: The Contested Countours of IP*. (CUP, 2014)

²³ Kathrine Strandburg (n 22).

²⁴ Pallin v. Singer, 1996 WL 274407 (D. Vt., Mar.28, 1996).

²⁵ Ibid.

²⁶ See for example German Federal Court of Justice (FCJ) decisions of July 11, 1995 (Klinische Versuche I) (Clinical Trials I), BGH NJW 1996, 782, and April 17, 1997 (Klinische Versuche II) (Clinical Trials II), BGH NJW 1997, 3092. For further discussion see: Hans-Rainer Jaenichen and Johann Pitz, 'Research Exemption/Experimental Use in the European Union: Patents Do Not Block the Progress of Science' (2015) 5(2) Cold Spring Harb Perspect Med. 1. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4315916/>.

but generally, it is significantly broader than in the US where as a general rule, only “philosophical enquiries” are allowed. One of the most significant variations between the research exemption provided for in European jurisdictions is to what extent the safe harbour for research *on* patented inventions is extended to also encompass research *with* patented inventions²⁷. Furthermore, some jurisdictions have introduced specific exemptions for use of *research tools* (Belgium, Italy) and *academia* (the Netherlands). The configuration of these parameters forms a European Research exemption landscape of considerable variation²⁸.

Furthermore, Article 53(c) of the European Patent Convention (EPC) exempts methods “for the treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body” from patentability. This provides a freedom to undertake the treatment of patients not only covering qualified medical practitioners. There is, however, some debate on what exactly “methods for the treatment of the human or animal body” and “method practiced on” means. Moreover, Article 53(c) further state that “this provision shall not apply to products, in particular substance or compositions, for use in any of these methods”. However, at least when looking at the scope of persons that may benefit from the exemption and in the size of the safe harbour carved out, i.e. providing an exemption to patentability rather than mere immunity from injunctions and damages, it could be argued that the European exemption in this field has a broader scope than the US immunity for medical practitioners.²⁹

3.2 *European Bolar provisions*

In Europe, a Bolar-type exemption is codified in EU directive 2001/83/EC as amended by directive 2004/27/EC. It was inspired by the US equivalent and is adopted in order to address the uncertainty pertaining to the application of the research exemptions to the preparatory steps for obtaining marketing approval. However, despite the intent to create more certainty, a number of uncertainties have blossomed in the wake of this initiative. Being based on a directive, the Bolar exemption has to be implemented in the various national legislations of the member states. This means in plain language that the national courts have the first say in the interpretation of the provision, whereas the Court of Justice of the European Union (CJEU) will have the last say. However, little case law has reached the CJEU yet, and thus different interpretations from national courts have created a complex legal landscape. Furthermore, the introduction of the Unified Patent Court (UPC) and Brexit provide political uncertainty as to the future interpretation of the Bolar-type provisions. It is possible that Bolar-type provisions will be harnessed to gain a national competitive edge creating further discrepancies between its interpretations in European jurisdiction. The following section will outline a few topical legal issues that require further clarification, while case law is still scarce.

²⁷ András Kupecz and others, ‘Safe Harbours in Europe: An Update on the Research and Bolar Exemptions to Patent Infringement.’ (2015) 33 *Nature Biotechnology* 710.

²⁸ For an elaborate comparison of the most important European jurisdictions see Kupecz and others (n 27).

²⁹ For elaboration on Article 53(c), see e.g. EPO guidelines for Examination, Part G, Chapter II, 4.2, http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4_2.htm. And for some further perspectives on the application of art 53 (c): Ana Norberg ‘Patentability of methods of human enhancement.’ (2015) 10 *Journal of Intellectual Property Law and Practice* 19.

3.3 *Does it take two to Bolar?: The 3rd party issues*

Who may benefit from the Bolar-type exemption? The pharmaceutical industry and in particular the biomedical sector is increasingly vertically disintegrated involving many different collaborators. It is however an open question whether the Bolar-type exemption applies to third parties involved in the development of e.g. a generic or biosimilar product. National courts have developed disparate approaches to these issues, and in 2015, the Polish Supreme Courts applied a narrow interpretation of the exemption.³⁰ Similar to the Polish Court, the German Düsseldorf regional court considered that such third party supply was only exempted by the Bolar provision under very restrictive conditions. The supplier should be co-organiser of the tests and studies carried out by its customer and only encompass tests and studies allowed under the Bolar exemption.³¹ Hence, the regional court decided that there was no need to refer the question of third party supply to the CJEU.

The Düsseldorf appeal court, however, disagreed. The appeal court found, that a narrow interpretation not allowing third parties to benefit from a Bolar-type exemption would be derogatory of competition and contrary to the purpose of the provision. Thus, third parties should be allowed to benefit from the Bolar-type exemption if certain requirements are met that ensures that a fair balance of interests is met. To benefit from the Bolar-type exemption, however, the third party supplier of e.g. an active ingredient should make reasonable measures to ensure that it is only used for the purpose of producing the regulatory data required for marketing approval. This could e.g. be by only supplying amounts of the active ingredient that seems appropriate for this purpose. Furthermore, limitations on the use should also be reflected in the contract between the parties.³²

Recognizing, however, that the nature of the issues stemming from an EU Directive would require answers from the CJEU, the appellate court decided to stay the proceedings and referred several questions to the CJEU for a preliminary ruling under Article 267 of the Treaty on the Functioning of the European Union (TFEU). The appeal court basically asked whether, in the case of a generic company seeking to be exempted from patent infringement under the Bolar exemption, a third party who supplies active ingredients to that company is also covered (C-661/13). Unfortunately, however, the case was subsequently settled and the referral was withdrawn. Thus, clarification as to whether the Polish narrow or the German broad interpretation will prevail is yet to be determined.

3.4 *Variation and 2nd indications*

European Bolar-type exemptions were created in order to allow generic competition to enter the market upon expiration of the patent protection of the originator product. However, does the Bolar-type exemption also apply if the use of the patented invention is for the purpose of conjuring data to get marketing approval for a second or further medical indication or for bioequivalents or biosimilars, which are not exact copies of the originator drug? This issue opens for a discussion of the purpose of the Bolar-type provisions to establish a proper interpretation and application of the exemption. Interpreted narrowly, Bolar-type exemptions should ensure that generic competition are available upon patent expiry, i.e. that generic producers can compete on equal terms with the originator upon the expiration of the originators patent(s) and avoid overcompensation of the originator. Interpreted broadly, Bolar-type exemptions can be regarded as a mean to enhance the efficiency of the innovation

³⁰ Polish Supreme Court, decision October 23, 2013 IV CSK 92/13.

³¹ Regional Court in Düsseldorf (Judgment of July 26, 2012, docket 4a O 282/10).

³² Higher Regional Court in Düsseldorf (Judgment of December 5, 2013, docket I-2 U 68/12).

system and ameliorate the unwarranted extended de facto exclusivity of the originator patent caused by the delay imposed by regulatory requirements. This broader interpretation also complements the patent law's basic notion, that the patent promotes disclosure of knowledge and enables others to stand on the shoulder of previous inventions. The general opinion seems to be that tests for second indications should benefit from the Bolar-type exemption in Europe³³. However, many issues in that regard would still have to be clarified through evolving case law.

3.5 *Post MA studies*

Another area where a narrow and a broad interpretation of the Bolar-type exemption subsist in parallel in Europe is whether the exemption applies to *studies conducted post-marketing approval*. As in the U.S., the E.U. regulatory system pertaining to the pharmaceutical sector continues to monitor pharmaceuticals after MA. The holder of the MA have substantial post-marketing obligations to monitor and collect data on the pharmaceutical. These procedure are commonly referred to as "pharmacovigilance". The collection and production of this data is an integrated part of the regulatory approval and a precondition of sustaining a MA for a pharmaceutical product. In 2014, the UK passed an amendment³⁴ to the regulation specifically allowing post-approval studies. However, such amendment has not been passed in Denmark nor been on the EU Commissions table. The general impression is, that – at least in Denmark - such studies will probably not be allowed to benefit from the Bolar exemption from patent infringement.³⁵

3.6 *Subsequent sale*

The production of patented inventions conducted under the Bolar exemption may amount to a substantial value. For example, in the biosimilar area it may be necessary to produce whole badges of biosimilars to demonstrate that the product in question is of a sufficient quality due to the often complicated production process. However, it is not clear whether such a badge may subsequently be sold after patent expiry. *On the one hand*, it could amount to a significant waste of resources to throw away a whole badge of biosimilars that may represent a substantial value. *On the other hand*, to allow such stockpiling may interfere with the fine line between the patent holders minimum rights following from Article 28 of the TRIPS agreement, and the allowance for limited exceptions in TRIPS art. 30. The central issues is whether such production is to be regarded as a form of stockpiling, and if so, whether it can be considered "limited" under TRIPS Article 30³⁶. A related issue is whether export of a patented substance produced under the Bolar exemption may subsequently be exported to a jurisdiction without patent protection of the invention. In May 2018 the EU commission announced a proposal for a "*targeted adjustment to the intellectual property rules*" allowing export to non-EU markets of pharmaceuticals protected by an EU supplementary protection certificate (SPC)³⁷. The

³³ Klaus Ewald Madsen, Webinar 28.11.2017.

³⁴ The UK regulation extends the scope of the experimental use exemption, but does only apply to medicinal products, see Section 60(6D) and (6E) Patents Act 1977.

³⁵ Klaus Ewald Madsen, Webinar 28.11.2017.

³⁶ See WTO Panel Report Canada – Patents Canada – Patent Protection of Pharmaceutical Products – Complaint by the European Communities and their Member States, WT/DS114/R, 17 March 2000, see: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm (accessed 9 July 2018).

³⁷ Commission, 'Pharmaceuticals: Commission refines intellectual property rules' IP/18/3907. Available here: http://europa.eu/rapid/press-release_IP-18-3907_en.htm; Commission, 'Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 Concerning the Supplementary Protection

purpose and rationale behind this initiative could also lever an argument for allowing the subsequent sale of products manufactured under the EU Bolar exemption, at least for export to non-EU markets. However, whether this line of argument will actually prevail is not clear and would need clarification from the CJEU or the Commission, taking into account the delicate balancing of TRIPS art 28 and 30.

3.7 *Medical devices*

Whereas the US Bolar exemption allows the use of a patented invention for the purpose of producing information required by a federal law, including medical devices³⁸, the EU equivalent are formulated in a significantly more narrow language. In EU, the Bolar exemption set out in Dir. 2001/83, Article 10(6) only applies to the conduct of the studies and clinical trials necessary to apply for a MA via the routes set out in Articles 10 (1) – (4), i.e. the abridged procedures for generics, bioequivalents and biosimilars. Thus, the European Bolar provision does not apply to medical devices, which are regulated by means of their own directive. On 5. April 2017, two new EU regulations on medical devices were adopted, replacing the existing directives: One regulation on medical devices and one on in vitro diagnostics³⁹. They will come into force after a transitional period of 3 years for medical devices and 5 years for in vitro diagnostics.

The new regulation on medical devices does not contain a Bolar-type exemption or anything similar for medical devices. However, the new regulations make extensive use of standardization schemes, e.g. CE marking etc., to ensure the safety, efficacy and quality of medical devices. Thus, if a medical device complies with the adopted standard, it will be assumed to be in congruence with the regulation. However, governance of technological systems via standards poses significant challenges⁴⁰, which are no less daunting than interpreting an exemption from patent infringement. IPR's may also apply to standards and the technology they refer to, potentially creating very strong constellations of market power, which will need to be addressed⁴¹. However, the evaluation of a regulatory regime for medical devices in EU should take into consideration the much broader research exemption in Europe, which may ameliorate some of the issues.

4. **Discussion/Concluding remarks**

Despite the different overall structure of the U.S. and European landscape, the challenges posed in the interpretation of the Bolar provisions in the respective territories have significant overlaps. Yet, these are addressed through somewhat different routes:

Certificate for Medicinal Products' COM(2018) 317 final. Available here:

<https://ec.europa.eu/docsroom/documents/29462>.

³⁸ Eli Lilly and Co. v. Medtronic, 496 US 661 (1990).

³⁹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [2017] *OJ L 117*; Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU [2017] *OJ L 117*.

⁴⁰ Timo Minssen and Jakob Wested, 'Standardization, IPRs and Open Innovation in Synthetic Biology' in Dana Beldiman (ed), *Innovation, Competition and Collaboration*. (Edward Elgar, 2015). Article is available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2153957.

⁴¹ The situation in the ICT industry may be worth considering, Where the issue of handling standard essential patent has been the subject of extensive and costly litigation.

For example, where Europe is still awaiting a “heads on” CJEU decision on *third party rights* within the Bolar exemption, U.S. attorneys have in general handled the issue proactively by e.g. hiring contract manufacturers as agents etc. The issue of *post-grant application* of Bolar exemptions does not seem to have found firm ground in either jurisdiction. The means to address these issues in EU and U.S. does seem somewhat different. In the U.S., MA applicants have the benefit of the broad Bolar exemption that exempts all use that is necessary due to federal law requirements. In Europe, the Bolar exemption only refers to the information necessary to get the MA. However, the tradition of significantly broader application of research exemption in Europe may alleviate some of this discrepancy. Meanwhile, the variation in national interpretation of the research exemption in Europe makes it a complex landscape to navigate. In US, the court decision in *Madey v. Duke*⁴² placed significant doubt on the reliance of research universities on the experimental use exception. Subsequently, the America Invents Act from 2011 altered § 102 of the US patent act creating doubts about the scope of public use defense in US patent law post-AIA⁴³. This possible change directly affect patent proprietors that wishes to conduct public experiments with their inventions to improve it before filing a patent application. However, it also adds to the impression that the US patent system is facing a possible recalibration of some of the basic features in the patent system regarding exceptions for various uses of invention pre- and post-patenting to accommodate an effective innovation system. This situation has created more emphasis on alternative and sector specific exemptions that may provide safe harbor for academic research as well as experiments necessary for improvements and generic competition, such as the state sovereign immunity under the Eleventh Amendment, which may be useful to public universities in the US⁴⁴ and the Bolar exemption.

From an international IP perspective post marketing approval use as well as subsequent sale of patented substances produced under the exemption of the Bolar provision, needs careful consideration of the requirements in the *TRIPS agreement*, in particular the minimum protection conferred by Article 28 and the option of providing limited exception to this protection in Article 30.

Generally, it should be stressed that the Bolar exemptions in Europe and US should be understood and evaluated in their broader context of international conventions as well as other available exemptions in the individual jurisdictions. Moreover, the cultures and practices pertaining to the specific fields of enquiry should be taken into account. Despite the very narrow research exemption in US, there is a long tradition among Universities to voluntarily impose restraints and adopt proactive policies in the governance of their patent portfolios, e.g. by offering fixed licensing and royalty rates, policies of non-exclusive licensing, and royalty free use for academic institutions⁴⁵. Furthermore, private companies have adopted similar lenient approaches to the use of their patented inventions, sometimes referred to as “rational forbearance” e.g. in relation to the non-assertion of PCR-patents

⁴² *Madey v. Duke Univ.*, 307 F.3d 1351, 2002 U.S. App. LEXIS 20823, 64 U.S.P.Q.2D (BNA) 1737 (Fed. Cir. Oct. 3, 2002).

⁴³ The US Supreme Court has granted certiorari to the case *Helsinn v. Teva*, where the issue of the intended scope of “public use” in the AIA is up for discussion. The case will be reheard in the autumn 2018.

⁴⁴ Kris J. Kostolansky and Daniel Salgado, ‘Does the experimental use exception in Patent Law have a future?’ (2018) 47(1) *The Colorado Lawyer* 32, available at: <https://blog.lrrc.com/ip/2018/01/11/experimental-use-exception-patent-law-future/>.

⁴⁵ See e.g. Sally Smith Hughes, ‘Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology. 1974-1980.’ (2001) 92 *Isis* 541; Jacob S Sherkow, ‘Law, History and Lessons in the CRISPR Patent Conflict.’ (2015) *Nature* 256.

on academic institutions⁴⁶. While these practices were adopted for some of the technologies that have enabled and developed the biotechnological area, recent scholarship has also demonstrated how commercial companies adopt the practice of patent pledging, providing customized safe harbours for investigation as well as innovation⁴⁷.

It will be interesting to follow the developments in the regulatory regime pertaining to medical devices, where it seems that EU and U.S. have adopted different paths of governance. The EU seems to have chosen an approach emphasizing technology governance and laying significant emphasis on the adoption of standards to govern the medical device area. In US, the existing model and inclusion of medical devices in the Bolar-exemption scheme sustains a more general, all-encompassing approach where the freedom of the market governs innovation.

Last but not least, we would like to stress how extraordinarily important the ongoing discussions about research- and Bolar-type exemptions have become in recent years. Many factors have contributed to this development, such as technical and scientific developments, e.g. in the gene editing and big data areas, recent court decisions and increasing attacks on the patent system within the health and life sciences. We believe that for the future such exceptions should be carefully considered in any new proposed laws or courts decisions that would have an impact on the scope of subject matter eligibility. Without well-balanced exceptions, the critics of broader eligibility will continue to argue that patents “preempt” basic research. Therefore, thorough comparative studies of other countries’ experimental use laws and court decisions seem more important than ever, to find out what those laws actually imply and whether those laws have created any uncertainty/problems in the courts and every day practice. In particular, further studies of these areas, which carefully consider different stakeholder’s interest and the complex mechanisms driving successful innovation systems, might encourage the U.S. Congress to consider whether the U.S. should also codify an “experimental use” exception for all technologies. Obviously, such exceptions should extend further than mere Bolar exemptions.

⁴⁶ Paul Rabinow, *Making PCR: A Story of Biotechnology*. (University of Chicago Press, 1996); Jakob Wested, ‘Applying Patents & Imagining Openness’ (Ph.D, University of Copenhagen 2017).

⁴⁷ Jorge L. Contreras and Meredith Jacob, (eds.) *Patent pledges: global perspectives on patent law’s private ordering frontier*. (Edward Elgar Publishing, 2017).